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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,873	11/21/2001	Tadashi Okamoto	35.C15961	9201

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,873	OKAMOTO ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/2120/01 and 03/04/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>03/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1-9, in papers filed 24 February 2003 is acknowledged.

The traversal is on the grounds(s) that the restriction standard set by MPEP § 806.05(f) requires restriction only between inventions that differ materially and that the office has not provided evidence that inventions of groups I and II differ materially or that the stated "direct deposit" would produce a product identical to that claimed. The argument has been considered but is not found persuasive because as stated in the restriction requirement the product of group II could be made by another and materially different process (e.g. direct deposit) as evidenced by the teaching of Egholm et al (U.S. Patent No. 6,297, 016, filed 8 October 1999) who teach an array of probes immobilized in an array having a labeling compound at a probe terminus (Column 5, lines 5-36 and Column 16, lines 60-Column 17, lines 34). The citation of Egholm et al is provided as evidence of processes of array production which differ materially from the invention of group II and is not considered as an exhaustive search and/or consideration of the subject matter of the invention of group II.

Applicant argues that the invention of group II would not be used by another and materially different process than that of groups III and IV. The argument has been considered but is not found persuasive because as stated in the restriction requirement the array of group II could be used for numerous and materially different process e.g. the array can be used to purify probe-binding agents, the array can be used a mother array from which daughter array are made, and the array can be used to synthesize probes complementary to the probes on the array.

Applicant argues that the inventions of groups I and IV and the inventions of groups III and IV are not distinct, but are at least somewhat connected in design, operation and effect

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because many of the features recited in the group I claims are similar to those of group IV. This is not found persuasive because dependent inventions may be properly restricted if they are distinct. As discussed in MPEP 803, one of the two criteria for requirement of restriction is that the "inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed". Accordingly, the demonstration of distinctness of the inventions is sufficient grounds for restriction. As stated in MPEP 802.01 "(t)he law has long been established that dependent inventions (frequently termed related inventions) such as those used for illustration above may be properly divided if they are, in fact "distinct" inventions, even though dependent".

Applicant further argues that it would not be undue burden to examine the claims of all groups I-IV. However, it is maintained that undue burden would be required to examine the claims of groups II, III and IV along with claims of group I as evidenced by the fact that the claims of groups I, II, III and IV have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of inventions II-IV. Specifically, a search of the subject matter of invention I would encompass nucleic acid, DNA oligonucleotide, peptide nucleic acid, protein and oligopeptide synthesis and labeling. In contrast, a search of the subject matter of invention II would encompass immobilized probes; a search of the subject matter of invention III would encompass measuring and quantifying labeled probes; and a search of the subject matter of invention IV would encompass probe-target interaction, measuring and quantifying labeled probes AND labeled targets and quantitative comparison between the probe and target labels. As such, a search for the subject matter of invention I would not be co-extensive with a search of the subject matter of inventions II-IV.

The requirement is still deemed proper and is therefore made FINAL.

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Drawings

2. The corrected or substitute drawings were received on 03/04/2002. These drawings are acceptable.

Specification

3. The disclosure is objected to because of the following informalities:

The nucleic acid sequences listed in the specification and drawings are not identified and/or labeled with their corresponding "SEQ ID NO:" as required (see, MPEP, 24223.03).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are indefinite in Claim 1 because the claim is drawn to a method of making a probe array but the method does not recite steps which make an array or probe array as claimed. Therefore, it is unclear whether the recited method steps result in the making a

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probe array. It is suggested that Claim 1 be amended to recite positive and active method step for making the array as detailed in the specification.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al (U.S. Patent No. 5,556,752, issued 17 September 1996).

Regarding Claim 1, Lockhart et al disclose a method of making a probe array for capturing a target substance comprising: synthesizing a plurality of probes immobilized at a plurality of matrix sites on a substrate by sequential synthesis wherein constitutional units are added one by one to a plurality of basal parts immobilized to the substrate until a desired length is obtained (Column 12) and coupling a labeling compound to a terminus of the probe of desired length (Column 19, lines 2-23 and Column 20, lines 4-21).

Regarding Claim 2, Lockhart et al disclose the method wherein the probe is a nucleic acid (Column 2, lines 31-40 and Column 20, lines 4-21).

Regarding Claim 3, Lockhart et al disclose the method wherein the nucleic acid is a DNA or an oligonucleotide (Column 2, lines 31-40 and Column 7, lines 43-47).

Regarding Claim 4, Lockhart et al disclose the method wherein the nucleic acid is a DNA and the synthesis is a phosphoramidite method comprising the steps of:

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(1) deprotecting hydroxyl groups bonded to the surface of a solid substrate via a linker (spacer); (2) coupling the deprotected hydroxyl group to the 3'phosphorous group of an amidite monomer having a desired base; (3) capping the hydroxyl groups not reacted in step 3; (4) oxidizing the coupled amidite in step (3) from phosphite to phosphate; (5) deprotecting a 5' hydroxyl moiety of the coupled amidite in step (2); (6) repeating steps (2) to (5) to obtain an oligonucleotide of a desired length and base sequence in a direction from 3' to 5'; and (7) deprotecting the bases (Column 12).

Regarding Claim 7, Lockhart et al teach their method wherein the labeled substance is a fluorescent substance known in the art (Column 17, line 61-Column 18, line 3).

Regarding Claim 8, Lockhart et al teach their method wherein the labeled substance is a fluorescent substance known in the art e.g. fluorescent dye (Column 17, lines 13-25 and Column 17, line 61-Column 18, line 3).

Regarding Claim 9, Lockhart et al teach the method wherein the labeled substance coupled to the terminus of the probe is different from the labeled substance coupled to the target (Column 18, lines 58-63).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al (U.S. Patent No. 5,556,752, issued 17 September 1996) in view of Zhang et al (U.S. Patent No. 6,251,583, filed 8 April 1999).

Regarding Claims 5 and 6, Lockhart et al teach the method of making a probe array for capturing a target substance comprising: synthesizing a plurality of probes immobilized at a plurality of matrix sites on a substrate by sequential synthesis wherein constitutional units are added one by one to a plurality of basal parts immobilized to the substrate until a desired length is obtained (Column 12) and coupling a labeling compound to a terminus of the probe of desired length (Column 19, lines 2-23 and Column 20, lines 4-21). Lockhart et al further teach their method encompasses proteins and oligopeptides (Column 5, lines 1-41) but they do not teach a specific embodiment utilizing proteins and/or oligopeptides. However, Zhang et al teach a similar method comprising synthesizing a plurality of immobilized probes on a matrix of a substrate by sequential synthesis wherein constitutional units are added one by one to a plurality of basal parts immobilized to the substrate until a desired length is obtained and coupling a labeling compound to a terminus of the probe of desired length (Column 11, line 20-Column 13, line 58) wherein the protein/oligopeptide probes are highly sensitive and specific detectors of HCV protease inhibitors. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the protein/oligopeptide probes of

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Zhang et al to the probe array of Lockhart and to synthesize protein/oligopeptide probes at multiple sites on their array to thereby a plurality of detect protease inhibitors simultaneously as desired by Zhang et al (Column 4, lines 38-60).

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Lizardi et al (U.S. Patent No. 6,403,319) disclose an array of probes synthesized on an array and labeled (Columns 11-14).


Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
March 28, 2003